

K962462

SEP 23 1996

Smith & Nephew DonJoy Inc.

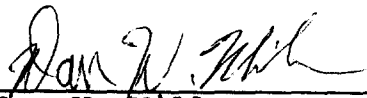
2777 Loker Avenue West  
Carlsbad, CA 92008-6601 U.S.A.  
Telephone: (619) 438-9091  
Toll-free: (800) 336-5690  
Telefax: (619) 438-3210

**Smith+Nephew**

K. SUMMARY OF SAFETY AND EFFECTIVENESS

The MuscleMax™ Plus is a disposable single patient use EMS (Electrical Muscle Stimulator) intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area. The output waveform consists of a 2200Hz biphasic, symmetrical one period signal (zero net DC component) in a series of low frequency (72 pps) bursts. Testing confirmed the device to fall within the acceptance criteria of 75μC for maximum charge per pulse when tested with a 500, 2K, and 10K Ohm load and the functional battery life of the device to exceed the minimum specification of 100 hours at maximum intensity. Because the wave is an alternating current, there is no net polar effects to cause long-term positive ion concentrations within the tissues beneath either electrode. The ON/OFF and intensity functions are controlled with a dial recessed into the housing to reduce the potential for inadvertent changes in intensity or accidental turning ON of the device. The unit has a green LED indicating when the unit is ON and releasing an electrical current, and a yellow LED indicating the unit is in the 20 second OFF cycle and will begin to release an electrical current within 20 seconds. The yellow LED warns the user not to increase the intensity until the green LED is illuminated to avoid inadvertent increases in output. The device is supplied with pre-gelled conductive electrode pads which have been cleared for marketing by the Food and Drug Administration under K912461. The electrode leads are strain relieved and designed to remain securely attached to the device (not removable), reducing the potential for attaching to AC power lines. The device is powered by four (4) 1.5 volt DC batteries contained within the housing.

Smith & Nephew DonJoy Inc.

  
Dan W. Miller  
Director of Regulatory Affairs  
and Quality Assurance

